

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
 United States Patent and Trademark
 Office
 Box PCT
 Washington, D.C. 20231
 ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 09 March 2000 (09.03.00)	
International application No. PCT/US99/15281	Applicant's or agent's file reference 029658/0142
International filing date (day/month/year) 07 July 1999 (07.07.99)	Priority date (day/month/year) 07 July 1998 (07.07.98)
Applicant EL-AMIN, Marianna et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

07 February 2000 (07.02.00)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
 34, chemin des Colombettes
 1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

R. Forax

Telephone No.: (41-22) 338.83.38

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 029658/0142	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US 99/ 15281	International filing date (day/month/year) 07/07/1999	(Earliest) Priority Date (day/month/year) 07/07/1998
Applicant LAMINA, INC. et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.
☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

IMPROVED METHODE FOR MIXING AND PROCESSING SPECIMEN SAMPLES

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☒ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1
☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/15281

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 G01N1/38 //A61B10/00,C12M1/26,C12Q1/24,C12M3/08,G01N33/48,
G01N33/54

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01N A61B B01L C12M C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A ✓	US 5 471 994 A (GUIRGUIS RAOUF A) 5 December 1995 (1995-12-05) cited in the application column 4, line 66 -column 5, line 39 column 6, line 3 -column 6, line 63 column 7, line 61 -column 8, line 35 column 8, line 46 -column 8, line 57 figures 1-10	1-4,6,7, 9,10
A ✓	US 4 845 025 A (LARY TODD P ET AL) 4 July 1989 (1989-07-04) column 3, line 49 -column 4, line 18 column 6, line 25 -column 7, line 3 column 7, line 59 -column 8, line 38 figures 1,11,16	1,3,5-7, 9

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Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

° Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

12 October 1999

Date of mailing of the international search report

20/10/1999

Name and mailing address of the ISA

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Authorized officer

Koch, A

INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A ✓	WO 94 20385 A (KVM TECHNOLOGIES INC) 15 September 1994 (1994-09-15) page 5, line 15 -page 5, line 35 page 6, paragraph 4 page 7, line 10 -page 8, line 1 page 8, line 31 -page 9, line 2 page 11, line 14 -page 12, line 11 page 13, paragraph 2 page 13, paragraph 4 page 16, line 32 -page 17, line 3 page 17, line 13 -page 17, line 19 page 17, line 28 -page 17, line 33 page 18, line 1 -page 18, line 28 page 20, line 22 -page 21, line 36 figures 9-12 ---	1,2,5,6, 8
A ✓	US 5 000 922 A (TURPEN JON) 19 March 1991 (1991-03-19) column 1, line 43 -column 2, line 48 column 3, line 10 -column 3, line 18 column 3, line 66 -column 4, line 35 column 5, line 4 -column 5, line 24 figure 1 ---	1,6-8
A ✓	EP 0 590 504 A (HOFFMANN LA ROCHE) 6 April 1994 (1994-04-06) column 1, line 1 -column 1, line 10 column 2, line 3 -column 2, line 43 column 6, line 30 -column 7, line 23 figures 1-13 -----	1,6,9,10

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/15281

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5471994 A	05-12-1995	US 5429803 A	04-07-1995
		US 5301685 A	12-04-1994
		US 5139031 A	18-08-1992
		US 5042502 A	27-08-1991
		US 4953561 A	04-09-1990
		US 5024238 A	18-06-1991
		US 4961432 A	09-10-1990
		AT 159588 T	15-11-1997
		AU 645689 B	20-01-1994
		AU 1781492 A	17-11-1992
		CA 2085741 A	19-10-1992
		DE 69222826 D	27-11-1997
		DE 69222826 T	19-02-1998
		EP 0535212 A	07-04-1993
		EP 0787987 A	06-08-1997
		JP 6501101 T	27-01-1994
		WO 9218844 A	29-10-1992
		US 5849505 A	15-12-1994
		AU 4777693 A	03-03-1994
		BR 9306818 A	08-12-1998
		CH 686324 A	29-02-1996
		EP 0654972 A	31-05-1995
		JP 8508395 T	10-09-1996
		WO 9403103 A	17-02-1994
		AU 1778992 A	02-11-1992
		CA 2084778 A	09-10-1992
		EP 0533912 A	31-03-1993
		JP 6500403 T	13-01-1994
		WO 9217110 A	15-10-1992
		AU 8046791 A	23-01-1992
		CA 2046833 A	19-01-1992
		EP 0468672 A	29-01-1992
		JP 6308126 A	04-11-1992
		US 5224489 A	06-07-1993
		AU 642904 B	04-11-1993
		AU 6300690 A	28-03-1991
		CA 2025261 A	23-03-1991
		EP 0425093 A	02-05-1991
		JP 3131760 A	05-06-1991
		AT 119071 T	15-03-1995
		AU 644096 B	02-12-1993
		AU 6252290 A	21-03-1991
		DE 69017334 D	06-04-1995
		DE 69017334 T	29-06-1995
		EP 0419168 A	27-03-1991
		ES 2072399 T	16-07-1995
		JP 3170060 A	23-07-1990
		US 5016644 A	21-05-1991
		US 5022411 A	11-06-1991
		US 5137031 A	11-08-1992
US 4845025 A	04-07-1989	AT 111223 T	15-09-1994
		AU 2710888 A	01-06-1989
		CA 1322325 A	21-09-1993
		DE 3851433 D	13-10-1994
		DE 3851433 T	19-01-1995
		EP 0353264 A	07-02-1990
		JP 6103299 B	14-12-1994

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/15281

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4845025 A		JP 2502126 T WO 8904484 A	12-07-1990 18-05-1989
WO 9420385 A	15-09-1994	AU 6444094 A CA 2157788 A EP 0688290 A JP 8507995 T US 5785044 A	26-09-1994 15-09-1994 27-12-1995 27-08-1996 28-07-1998
US 5000922 A	19-03-1991	US 5112490 A	12-05-1992
EP 0590504 A	06-04-1994	US 5356814 A CA 2105826 A,C DE 69315521 D DE 69315521 T ES 2111680 T JP 2837076 B JP 6213788 A	18-10-1994 30-03-1994 15-01-1998 18-06-1998 16-03-1998 14-12-1998 05-08-1994

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 029658/0142	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/15281	International filing date (day/month/year) 07/07/1999	Priority date (day/month/year) 07/07/1998
International Patent Classification (IPC) or national classification and IPC G01N1/38		
Applicant LAMINA, INC. et al.		



1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 28 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 07/02/2000	Date of completion of this report 11.10.2000
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Huenges, A Telephone No. +49 89 2399 2280 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/15281

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1,6,10,21,24-27	as originally filed	
2,2a,3-5,7-9,11-14, 14a,15-20,22,23, 28	with telefax of	02/08/2000

Claims, No.:

1-7	with telefax of	02/08/2000
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Drawings, sheets:

3/5	as originally filed	
1/5,2/5,4/5,5/5	with telefax of	02/08/2000

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/15281

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 1-7
	No: Claims
Inventive step (IS)	Yes: Claims 1-7
	No: Claims
Industrial applicability (IA)	Yes: Claims 1-7
	No: Claims

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

1. Reference is made to the following documents:

D1: US-A-5 471 994 (GUIRGUIS RAOUF A) 5 December 1995 (1995-12-05)
cited in the application
D2: US-A-4 845 025 (LARY TODD P ET AL) 4 July 1989 (1989-07-04)
D3: WO 94 20385 A (KVM TECHNOLOGIES INC) 15 September 1994 (1994-09-15)
D4: US-A-5 000 922 (TURPEN JON) 19 March 1991 (1991-03-19)
D5: EP-A-0 590 504 (HOFFMANN LA ROCHE) 6 April 1994 (1994-04-06)

2. The invention relates to a method for separating particulate matter from a fluid and for collecting a substantially uniform layer of particulate matter on a collection site using an apparatus comprising a mixing device having on top of it a porous arrangement and a pump for drawing the dispersed fluid through the porous arrangement. The method further comprises the exposure of the collection site and the transfer of the collected matter onto a microscopic slide.
3. Document D1, which is considered to represent the most relevant state of the art, discloses (cf. fig. 8) a method for obtaining a cytology monolayer comprising the steps of drawing dispersed particulate matter through a filter assembly, thereby capturing the particulate matter on a collection surface (col. 5, lines 5-13), exposing the collection site (col. 8, lines 22-28) and transferring the particulate matter onto a microscope slide (col. 7, line 61 - col. 8, line 3 and col. 8, lines 24-32).

The further prior art relates to mixing of fluids (D2), to filtering and dispensing a sample into a fluid (D4), to the disaggregation of cytological specimen (D5) and to a fluid sample receptacle (D3).

4. The subject-matter of claim 1 differs (Art. 33(2) PCT) from that known from document D1 in the specific arrangement of specimen container, dispersing element and mixer as set out in the claim, thus providing an improved method for collecting and processing a uniform layer of particulate matter originally kept in a

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US99/15281

fluid using the same apparatus for dispersing the particulate matter and collecting it on a collection site.

The subject-matter of claim 1 is considered as involving an inventive step (Article 33(3) PCT) because neither D1 nor the further prior art cited in the search report hint at the use of an apparatus incorporating the special features as set out in the claim.

5. **Claims 2-7** are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.
6. The industrial applicability of the claimed invention is beyond doubt, Art. 33(4) PCT.

Re Item VII

1. Document D1 is still not sufficiently discussed in the description, Rule 5.1(a)(ii) PCT, as it discloses the following features:
 - drawing the sample containing dispersed particulate matter through a filter assembly located in a housing atop the cover, whereby the particulate matter is captured in a substantially uniform layer on a collection surface (col. 5, lines 5-13 and col. 8, lines 6-10 and fig. 8 together with the accompanying description),
 - exposing the layer of particulate matter on the collection site (col. 8, lines 22-28) and
 - placing the exposed layer of particulate matter in contact with a microscope slide whereby the captured particulate is transferred from the collection site to the microscope slide (col. 7, line 61 - col. 8, line 3 and col. 8, lines 24-32).In addition, the description on page 2, lines 27-29 of the present application is in contradiction to said disclosure.
2. According to the requirements of Rule 11.13(m) PCT the same feature shall be denoted by the same reference sign throughout the application. This requirement is not met in respect of the "specimen container" bearing reference sign number 20 on page 11, line 16 and reference sign number 10 on page 18, line 22.

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3. According to the requirements of Rule 11.13(I) reference signs not appearing in the description shall not appear in the drawings, and vice versa. This requirement is not met in view of reference sign numbers 36 (page 16, line 31 and page 17, lines 1, 4 and 15) and 37 (page 17, lines 2, 3 and 16).
4. Although all claims are directed to a method, the description is not in agreement therewith to the extent that throughout the description also an apparatus and testing kit are said to be part of the invention (see e.g. page 7, lines 5-6, 12 and 27 and page 8, lines 4, 9, 12, 21, 25 and 30).

Re Item VIII

The device described on page 7, lines 12-26 does not contain a mixer and therefore does not fall within the scope of the claims. The same holds for the embodiment described on page 15, line 30 - page 16, line 7 as the particulate matter is collected in a "predetermined configuration or spatial distribution" and not in a uniform layer. This inconsistency between the claims and the description leads to doubt concerning the matter for which protection is sought, thereby rendering the claims unclear (Article 6 PCT).